



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 6, 2015

Wendy Garman
Vice President, Regulatory Affairs
Sybron Dental Specialties
Metrex Research
1717 West Collins Avenue
Orange, CA 92867

Subject: Label Amendment – Revise use directions to include two wipe step
Product Name: CAVIWIPES
EPA Registration Number: 46781-8
Application Date: December 1, 2014
Decision Number: 498553

Dear Ms. Garman:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

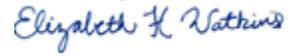
A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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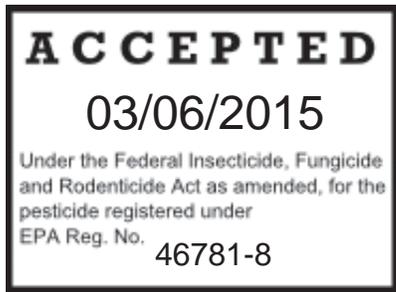
Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Elizabeth Watkins by phone at 703-347-0241, or via email at Watkins.Elizabeth@epa.gov.

Sincerely,



Elizabeth Watkins
Acting Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure



CAVIWIPES

[[Extra large] Disinfecting Towelettes]
[Kitchen** and Bath Wipes]
[Kitchen** and Bath Wipes for Hard, Non-Porous Surfaces]
[Cleans, Deodorizes and Kills Common Household Germs]

[The descriptive terms below are to be used, as applicable, depending on the microorganisms listed on the production label.]

[TUBERCULOCIDAL] [[•] BACTERICIDAL] [[• VIRUCIDAL*] [[• FUNGICIDAL]

[For Professional Use]
[For Household Use]
[For Professional and Household Use]

ACTIVE INGREDIENTS:

| | |
|--|----------------|
| Diisobutylphenoxyethoxyethyl dimethyl benzyl ammonium chloride | 0.28% |
| Isopropanol | 17.20% |
| INERT INGREDIENTS†: | 82.52% |
| TOTAL | 100.00% |

† Does not include the weight of the dry [towelette] [[or] wipe].

KEEP OUT OF REACH OF CHILDREN

CAUTION

[See other panel for additional precautionary statements.]

EPA Reg. No. 46781-8
EPA Est. No. 56952-WI-001 • [71979-SC-001] [•75272-WI-001] [• 51435-WI-004]

Reorder No.

Net Contents: # [[lbs.] [oz]]
Pre-Saturated Towelette # x # in.

[Packed For:] Metrex Research Corporation
[Distributed By:] 28210 Wick Road
[Sold By:] Romulus, Michigan 48174

[For product or technical information, contact Metrex at **800-841-1428** or visit our web site at **www.metrex.com.**]

THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING
Statements in brackets, [], are optional or instructional. Italicized words in brackets are not included on production labels. Sequence of statements is optional unless specified in 40 CFR 156.10. Capitalizing, pluralizing, singularizing, bolding, italicizing and abbreviating are variable unless specified in 40 CFR. Lists of uses and use sites may be used partially or in their entirety.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse. [See other panel for additional precautionary statements.]

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for further advice.

If on skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

For Chemical Emergency ONLY (spill, leak, fire, exposure or accident), call CHEMTREC at 1-800-424-9300. For ALL other inquiries about this product, call Metrex Customer Service at 1-800-841-1428, Monday through Friday, between 6 a.m. and 4 p.m. Pacific Time.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

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[**CaviWipes** Disinfecting Towelettes are non-woven disposable towelettes pre-saturated with **CaviCide**.]

CaviWipes are intended for use in [health care settings such as [hospitals,] [laboratories,] [clinics,] [dental offices,] [ophthalmic offices] [and veterinary facilities]] [, [and in] [kitchens** and bathrooms]].

[**CaviWipes** are effective against the following microorganisms on hard, non-porous surfaces when used as directed:

[Mycobacterium tuberculosis var: bovis (BCG)]

[Staphylococcus aureus]

[Pseudomonas aeruginosa]

[Salmonella enterica]

[Trichophyton mentagrophytes]

[Methicillin Resistant Staphylococcus aureus (MRSA)]

[Vancomycin Resistant Enterococcus faecalis (VRE)]

[Staphylococcus aureus with reduced susceptibility to vancomycin]

[Hepatitis B Virus (HBV)*]

[Hepatitis C Virus (HCV)*]

[Herpes Simplex Virus Types 1 and 2*]

[Human Immunodeficiency Virus (HIV-1)*]

[Influenza A2 Virus*]]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

[**CaviWipes** Disinfecting Towelettes are non-woven disposable towelettes pre-saturated with **CaviCide**.]

CaviWipes are intended for use on hard, non-porous surfaces in [health care settings such as hospitals,] [emergency medical settings,] [neonatal units,] [surgical centers,] [isolation areas,] [out-patient surgical centers (OPSC),] [laboratories,] [clinics,] [nursing homes,] [dental offices,] [ophthalmic offices,] [eye surgical centers,] [patient care areas,] [dialysis centers,] [donation centers (blood, plasma, semen, milk, aphaeresis),] [veterinary facilities,] [[salon settings,] [emergency vehicles,] [correctional facilities,] [schools,] [health club facilities,] [tanning salons,] [kitchens**,] [non-food contact surfaces in food preparation areas**,] [bathrooms,] [daycare centers,] [police and fire vehicles,] [morgues,] [cadaver processing areas,] [funeral homes,] [laundry rooms,] [pet areas]] and other critical care areas where control of cross contamination between treated surfaces is required.

[Listing of at least one of the following equipment/instruments/hard, non-porous surfaces on production labels is required. The last equipment/instruments/hard, non-porous surface listed will be preceded with the word "and".]

CaviWipes will clean and disinfect, when used as directed, such items as [interior and exterior surfaces of infant incubators, bassinets, cribs and warmers,] [infant/child care equipment surfaces,] [diaper changing stations,] [diaper pails,] [high chairs,] [oxygen hoods,] [operating room tables and lights,] [laboratory equipment and surfaces,] [physical therapy (PT) equipment surfaces,] [spine back boards,] [ambulance equipment surfaces,] [slit lamps,] [eye glasses (do not use on contact lenses),] [hard, non-porous exterior surfaces of ultrasound transducers or probes,] [exam tables,] [gurneys,] [IV poles,] [dental unit instrument trays,] [operator light switches,] [exterior surfaces of amalgamators and dental curing

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lights,] [exterior surfaces of anesthesia machines and respiratory therapy equipment,] [SilkPeel™ with DermallInfusion™,] [workstations,] [dental countertops,] [dental chairs,] [loupes,] [exterior surfaces of endodontic equipment, such as apex locators, pulp testers and motors,] [stools,] [nail/hair care implements,] [tanning beds,] [hair dryers,] [hair clippers,] [shears,] [razors,] [hair cutting implements,] [clipper blades,] [salon surfaces,] [scissors,] [combs,] [brushes,] [manicure implements,] [washable nail files,]

[non-food contact surfaces**,] [exterior surfaces of refrigerator units**,] [exterior surfaces of appliances such as refrigerators, microwaves, food processors and stoves**,] [vanity tops**,] [tiles**,] [floors,] [walls,] [handrails,] [door knobs,] [bed railings,] [tables,] [chairs,] [faucets,] [bathroom fixtures,] [exterior toilet surfaces,] [garbage cans,] [computers,] [keyboards,] [carts,] [baskets,] [grocery carts,] [shopping carts,] [weight-lifting surfaces,] [drained whirlpool tank surfaces,] [cabinets,] [lights,] [telephones,] which are made of plastic (i.e., polycarbonate, polypropylene, polyvinylchloride, polystyrene), and use sites listed on this label consisting of non-porous vinyl, stainless steel, painted surfaces, Plexiglas®, Formica® and glass. **DO NOT USE AS A BABY WIPE. [Not For Use On Skin]**

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[Use A or B as applicable depending on the container type.]

[A - canister]

Dispenser Directions:

To start feed, remove cover and discard seal. From center of towelette roll, pull up a towelette corner, twist it into a point and thread it through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first towelette and tear off at a 90° angle. Remaining towelettes feed automatically, ready for next use. When not in use, keep center cap closed to prevent solution loss.

Cleaning Instructions:

Use one **CaviWipes** towelette to completely pre-clean surface of all gross debris.

For use as a virucide*, including HIV-1, HBV and HCV applications and effectiveness against Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin Resistant *Enterococcus faecalis* (VRE) and *Staphylococcus aureus* with reduced susceptibility to vancomycin: Use a second CaviWipes towelette to thoroughly wet the surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 2 minutes at room temperature (69°F/20°C).

For use as a disinfectant:

CaviWipes is a two-step disinfectant product. One wipe is required to pre-clean then a second wipe is required to disinfect. Repeated use of the product may be required to ensure that the surface remains visibly wet for 3 minutes at room temperature (69°F/20°C) for Tuberculocidal** activity and effectiveness against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes* and *Salmonella enterica*.

[B - packet]

Packet Directions:

Open packet, remove towelette and unfold.

Cleaning Instructions:

Use one CaviWipes towelette to completely pre-clean surface of all gross debris.

For use as a virucide*, including HIV-1, HBV and HCV applications and effectiveness against Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin Resistant *Enterococcus faecalis* (VRE) and *Staphylococcus aureus* with reduced susceptibility to vancomycin: Use a second CaviWipes towelette to thoroughly wet the surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 2 minutes at room temperature (69°F/20°C).

For use as a disinfectant:

CaviWipes is a two-step disinfectant product. One wipe is required to pre-clean then a second wipe is required to disinfect. Repeated use of the product may be required to ensure that the surface remains visibly wet for 3 minutes at room temperature (69°F/20°C) for Tuberculocidal** activity and effectiveness against *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Trichophyton mentagrophytes* and *Salmonella enterica*.

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[The following direction is to be included when hard, non-porous exterior surfaces of ultrasound transducers or probes is listed as a use site.]

[To disinfect external surfaces of ultrasound transducers: Pre-clean ultrasound gel from external transducer to be disinfected [by using a clean wash cloth]. Then thoroughly wet the probe with a Caviwipes towelette and allow the precleaned surface. Repeated use of the product may be required to ensure that the surface remains visibly wet for 3 minutes at 20°C.]

[The following statement is to be included on production labels when food contact surfaces are listed.]

[** A thorough rinse with potable water is required for surfaces in direct contact with food.]

[The following HIV / HBV / HCV instructions are to be included on production labels when claims against HIV or HBV or HCV are listed.]

CaviWipes effectively kills [Human Immunodeficiency Virus Type 1 (HIV),] [Hepatitis B Virus (HBV),] [[and] Hepatitis C Virus (HCV)] on precleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects can be associated with the potential for transmission of [HIV,] [HBV,] [[and] [HCV].

Special Instructions for Cleaning and Decontamination Against [HIV-1,] [HBV,] [[and] HCV] of Surfaces or Objects Soiled With Blood or Body Fluids:

Personal Protection: When using this disinfecting towelette, wear appropriate barrier protection such as disposable protective gloves, protective gown, face mask and eye covering.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfecting towelette. A **CaviWipes** towelette can be used for this purpose.

Contact Time: Thoroughly wet surface with a new **CaviWipes** towelette. Repeated use of the product may be required to ensure that the surface remains visibly wet for 2 minutes. This contact time will not be sufficient for some of the organisms listed on the label. Refer to label for contact times against other organisms.

Disposal of Infectious Materials: Cleaning materials used that may contain blood or other body fluids must be autoclaved and disposed of in accordance with Federal, State and local regulations for infectious materials disposal.

[The following paragraph will be included in its entirety when the production label references health care use.]

This product is not to be used as a terminal sterilant/ high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection.

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[Use A or B as applicable depending on the container type.]

[A - canister]

STORAGE AND DISPOSAL

Towelette - Do not reuse towelette. Dispose of used towelette in trash.

Dispenser - Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. [Wrap container and discard in trash.]

[B - packet]

STORAGE AND DISPOSAL

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

Towelette - Do not reuse towelette. Dispose of used towelette and empty packet in trash.

[The following graphics are optional for canister containers only. They will be affixed to the label/canister so that it does not interfere with any label text. Due to size constraints, they will not appear on individually wrapped packets.]



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